510(k) Summary

A.B. Korkor Medical, Inc. AngioXpand Introducer Catheter

This 510(k) summary of the safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92

The assigned 510(k) number is: K092097

MAY - 6 2010

Contact Person: Andy Black
Medical Murray, Inc.
400 North Rand Road
North Barrington, IL 60010

Telephone: (847) 620-7990
Fax: (847) 620-7995

Date Prepared: April 9, 2010

Device Name and Classification

Classification Name:	Introducer, Catheter
Common/Usual Name:	Introducer Catheter
Proprietary Name:	AngioXpand Introducer Catheter
Device Classification:	Class II
Regulation Number	21 CFR Ref. § 870.1340
Product Code:	DYB
Panel:	Cardiovascular

Device Description

The AngioXpand Introducer Catheter is a medical device composed of a disposable needle and catheter. The device is equivalent in intended use to current legally marketed introducer catheter devices, and utilizes the same catheter-over-needle form as other legally marketed devices.

The AngioXpand Introducer Catheter decreases the range of introducing needle sizes required during patient cannulation. The system is expected to provide a patient the benefit realized by decreasing the size of the introducing needle required of larger gauge introducers.

An appropriate sized guidewire or dilator becomes the means of expanding the introducer's tip, allowing passage of a catheter or guidewire into the blood vessel. This action permits the initial size of the needle to be smaller than the desired placed catheter size.

Substantial Equivalence Claim

Based on comparison of device features, materials, intended use and performance, the A.B. Korkor Medical, Inc. AngioXpand Introducer Catheter is shown to be substantially equivalent to the commercially available predicate device BD Introsyte Precision Introducer Catheter approved by the FDA under 510k number K020834.

Indications for Use

The AngioXpand Introducer Catheter is intended to facilitate placement of other devices such as guidewires or catheters through the skin into the vascular system.

Summary of Testing

The AngioXpand Introducer Catheter has been tested in accordance with applicable standards.

Data has been provided to demonstrate that product performance and safety are substantially equivalent to current legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MAY - 6 2010

A. B. Korkor Medical, Inc
c/o Mr. Mark Job
1394 25th St. NW
Buffalo, MN 55313

Re: K092097
Trade/Device Name: AngioXpand® Introducer Catheter
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: April 9, 2010
Received: April 12, 2010

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. However, we remind you that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

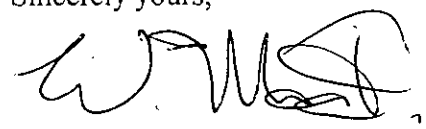
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K092097

Device Name: A.B. Korkor Medical AngioXpand Introducer Catheter

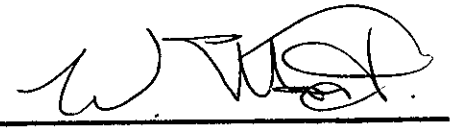
Indications for Use:

The AngioXpand Introducer Catheter is intended to facilitate placement of other devices such as guidewires or catheters through the skin into the vascular system.

Prescription Use __X__ AND/OR Over The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092097